

In the United States Patent and Trademark Office

Applicant: Siegel
Serial No.: Unknown
Filed: Herewith
For: Process and Composition for Removing Biofilm

Box New Application-Fee
Commissioner for Patents
Washington, DC, 20231

Preliminary Amendment

In connection with the above-identified application, kindly enter the following amendment.

In the Title

Rewrite the title to read:

--Process and Composition for Removing Biofilm--

In the Specification

On page 1, second paragraph, rewrite as follows:

--This application is a continuation-in-part of application Serial No. 09/089,845, filed 06/03/1998, now abandoned, and a continuation-in-part of application Serial No. 09/608,048 filed 08/30/2000.--

--Summary of the Invention

The present invention relates to a composition and process for removing biofilm from a medical unit water line and to reduce microbial iodide salt. The composition

consists an aqueous acidic solution containing a monobasic iodide salt, an organic acid, at least one oxidizing agent and an inorganic buffer comprising phosphate salts.

More particularly, the monobasic iodide salt comprises at least about 0.01 to 0.5% by weight of the composition. The organic acid comprises at least about 0.1 to 1.0% by weight of composition. The oxidizing agent comprises at least about 0.02 to 0.5% by weight of composition and the composition is buffered to a pH between 2 and 5. The composition precludes persulfate salts since they react with the iodide salt and cannot be packed together.

Preferably the composition of the present invention is dissolved in water to equal one liter prior to use--.

On page 9, delete lines 1-6. One page 9 after line 11, insert:

--The present invention provides an antimicrobial composition for removing biofilm from a medical water line comprising an aqueous acidic solution containing an effective amount of a monobasic iodide salt, an effective amount of an organic acid, an effective amount of at least one oxidizing agent and an inorganic phosphate buffer. Preferably, the pH of the solution is about 2 to 5, is utilized in an effective amount to remove biofilm material and the oxidizing agent is free of persulfate salts.

More particularly, the composition comprises a monobasic iodide salt which is an alkali material salt, preferably sodium or potassium iodide in an amount of at least about 0.01% to 0.5% by weight, more preferably about 0.01 to 0.1%. The composition contains an organic acid containing up to three carboxylic acid groups having up to six carbon atoms, preferably selected from the group consisting of citric acid, ascorbic acid, and oxalic acid in an amount of about 0.1 to 1% by weight, preferably 0.1 to 0.5%.

The oxidizing agent is the alkali metal salt of a perborate or percarbonate or urea hydroxy peroxide which is present in an amount of at least about 0.001 to 0.01% by weight of a member selected from the group consisting of sodium percarbonate, sodium perborate and urea hydrogen peroxide and mixtures thereof.

The inorganic phosphate buffer comprises a mono or dibasic potassium hydrogen phosphate in an amount to provide a pH between about 2 to 5.

A preferred composition for removing biofilm from a medical unit water line consists essentially of about 0.025% by weight of sodium iodide, about 0.16% by weight of citric acid and about 0.005% by weight of a mono and/or dibasic alkali metal salt of hydrogen phosphate, preferably, sodium perborate and potassium hydrogen phosphate salt, and a pH of about 3.5.

It is understood that the percents stated herein are by weight of composition unless indicated otherwise.--

On page 13, rewrite lines 16-22 as follows:

--Results: Biofilm water samples of the evaluated DUWLs demonstrated a mean count of --2,000,000 CFU/ml. Disinfection of DUWL with CIPP225 dramatically reduced cultivable bacteria by 5-6 logs, and with one exception, to <100 CFU/ml. SEMs of untreated DUWLs demonstrated mature biofilm comprises of multi-layered microcolonies including: curved rods, cocci, spirochetes and matrix material. This study has been published in Sanford et al, 1999 OSAP Annual Symposium Infection Control Interation, June 23-27, 1999 Cincinnati, Ohio.

On page 13, rewrite lines 26-28 to read as follows:

--A study similar to that described in Example 1 was performed three CIPP225 treatment frequencies: daily, twice weekly, and weekly. The number of samples containing high bacterial levels increases as the treatment frequency declines.--

In the Claims

Cancel claims 5, 6, 8-15, and 17-24 without prejudice and add the following new claims:

--25. An antimicrobial composition for removing biofilm from a medical line which comprises an acidic solution comprising:

- 1) an effective amount of a monobasic iodide salt;
- 2) an effective amount of an organic acid having up to six carbon atoms;
- 3) an effective amount of at least one oxidizing agent, and;
- 4) an inorganic phosphate buffer

said solution having a pH of about 2 to 5, and said composition being free of persulfate salts.

26. The composition of claim 25 wherein said iodide salt is an alkali metal salt in an amount of at least 0.01 to 0.5% by weight of composition and said organic acid is a dicarboxylic acid in an amount of about 0.1 to 1% by weight.

27. The composition of claim 25 wherein said organic acid is selected from the group consisting of citric acid, ascorbic acid, and oxalic acid.

28. The composition of claim 25 wherein said oxidizing agent is selected from the group consisting of sodium percarbonate, sodium perborate, urea hydrogen peroxide and mixtures thereof.

29. The composition of claim 25 wherein said buffer is selected from the group consisting of mono and dibasic alkali metal hydrogen phosphate salts.

30. The composition of claim 29 wherein said buffer is potassium hydrogen phosphate.

31. A method for removing biofilm from a medical line which comprises treating said medical line with composition of claim 25 in an effective amount to remove biofilm.

32. A method for removing biofilm from a medical line which comprises treating the medical line with an effective amount of the composition of claim 26.--

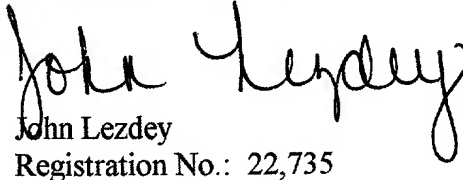
Remarks

The application has been amended so as to better claim the invention to scope that the applicants have been entitled to claim and to more clearly define the invention over the prior art.

Attached is a sheet entitled "Version With Markings To Show Changes Made".

Prosecution on the merits is now requested.

Respectfully submitted,


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Version With Markings To Show Changes Made

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The title has been rewritten as follows:

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--Results: Biofilm water samples of the evaluated DUWLs demonstrated a mean count of --2,000,000 CFU/ml. Disinfection of DUWL with CIPP225 dramatically reduced cultivable bacteria by 5-6 logs, and with one exception, to <100 CFU/ml. SEMs of untreated DUWLs demonstrated mature biofilm comprises of multi-layered microcolonies including: curved rods, cocci, spirochetes and matrix material. ~~Images of biofilm from the treated and untreated DUWLs are shown in Fig. 1 and Fig. 2, respectively.~~ This study has been published in Sanford et al, 1999 OSAP Annual Symposium Infection Control Interaction, June 23-27, 1999 Cincinnati, Ohio.

On page 13, lines 26-28 were rewritten to read as follows:

Example 4

~~Reduced Treatment Study~~

--A study similar to that described in Example 1 was performed three CIPP225 treatment frequencies: daily, twice weekly, and weekly. ~~As depicted in Fig. 3, the~~ The number of samples containing high bacterial levels increases as the treatment frequency declines.--

In the Claims

Claims 5, 6, 8-15, and 17-24 have been cancelled.

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